

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION)	
)	
)	
)	MDL No. 2419
)	Dkt. No. 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO:)	
)	
All Cases Against the Saint Thomas Defendants)	
)	

**MEMORANDUM OF LAW SUPPORTING MOTION FOR PARTIAL SUMMARY
JUDGMENT REGARDING COMPARATIVE FAULT DEFENSES ATTRIBUTING
FAULT TO GOVERNMENTAL ENTITIES**

The Plaintiffs’ Steering Committee respectfully submits this memorandum in support of its contemporaneously filed Motion for Partial Summary Judgment Regarding Comparative Fault Defenses Attributing Fault to Governmental Entities.

INTRODUCTION AND SUMMARY

Contrary to well-settled principles of Tennessee law, the Saint Thomas Defendants¹ assert the affirmative defense of comparative fault against the following governmental entities: the Food and Drug Administration (the “FDA”), the Massachusetts Board of Registration in Pharmacy (the “MBoP”), the Tennessee Board of Pharmacy (the “TBoP”), and the Tennessee Department of Health (the “TDoH”, and collectively with the FDA, MBoP, and the TBoP, the “Non-Party Governmental Entities”). Through those affirmative defenses, the Saint Thomas Defendants intend to ask juries to allocate fault on verdict forms to non-party government regulators. This Court should overrule those affirmative defenses because they are contrary to Tennessee law.

¹ The “Saint Thomas Defendants” include the Saint Thomas Outpatient Neurosurgical Center, LLC, Vaughan A. Allen, M.D., John Culclasure, Howell Allen Clinic, A Professional Corporation, and Debra Schamberg, as well as Saint Thomas Hospital West f/k/a Saint Thomas Hospital, Saint Thomas Network, and Saint Thomas Health

Under Tennessee law, fault cannot be attributed to government agencies because none of those agencies owed an individual legal duty to any particular plaintiff.

Under Tennessee's public duty doctrine, the only legal duty owed by the government was owed to the general public at large, not to any particular individual. In other words, a duty owed to everyone is a duty owed to no one particular person as far as Tennessee tort law is concerned. Accordingly, because legal duty is an essential element of fault, fault cannot be allocated to governmental entities at trial.

In addition, the Saint Thomas Defendants have failed to offer any evidence that any action or failure to act on behalf of the TBoP or the TDoH caused or contributed to the cause of plaintiffs' injuries. Therefore, summary judgment is appropriate as to those entities as there is no proof in the record to support a defense of comparative fault against them.

MATERIAL UNDISPUTED FACTS

In their Answers to plaintiffs' Master Complaint, the Saint Thomas Defendants assert the affirmative defense of comparative fault against the FDA, the MBoP, the TBoP, and the TDH.² Those allegations largely relate to the Saint Thomas Defendants' claims that those Non-Party Governmental Entities should have acted sooner and shut down NECC before the catastrophe that gave rise to this MDL.

Specifically, the Saint Thomas Defendants allege the following with regard to the FDA:

36. ...[The FDA] owed a duty to the Plaintiffs as well as their health care providers to ensure that MPA manufactured, sold, and distributed by NECC was sterile and safe for its intended use pursuant to the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 301, et seq.

² Doc. 1455 - Answer Of Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic, A Professional Corporation, John W. Culclasure, MD, and Debra V. Schamberg, RN, pp. 79 – 102 (hereinafter the "St. Thomas Neurosurgical Answer"); Doc. 1464 – Saint Thomas Entities Master Answer and Affirmative Defenses to Plaintiffs' Amended Master Complaint, pp. 101 – 117 (hereinafter the "Saint Thomas Entities Answer").

...

38. The Defendants assert comparative fault against the FDA for proximately causing the alleged injuries and damages by negligently or recklessly failing to take action against NECC even though the FDA had authority to do so...³

The Saint Thomas Defendants allege similar allegations against the MBoP and the TBoP:

56. [The MBoP] owed a duty to the Plaintiffs as well as their health care providers to ensure that NECC compounded medication free from contamination and operated in compliance with applicable Massachusetts pharmaceutical laws pursuant to Mass. Gen. Laws ch. 112, § 32.

....

66. The Mass. BoP proximately caused the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC after becoming aware of NECC's failure to comply with applicable state and federal laws and manufacturing guidelines...

....

72. [The TBoP] had the legal authority to inspect NECC, which was doing business in Tennessee as a licensee of the Tenn. BoP.

...

74. If it is established that the Tenn. BoP breached its duty by failing to timely investigate and bring charges against NECC for the violations outlined herein, failing to inquire of the Mass. BoP regarding actions against NECC, or failing to inspect NECC's facility, the Defendants assert fault against the Tenn. BoP.⁴

The Saint Thomas Defendants also allege comparative fault against the Tennessee Department of Health based on the following allegations:

³ Dkt. No. 1455, St. Thomas Neurosurgical Answer, Pg. 79 at ¶¶ 36, 38; The Saint Thomas Entities Answer contains nearly identical allegations. Dkt. No. 1464, St. Thomas Entities Answer, Pg. 101 at ¶¶ 250, 252.

⁴ Dkt. No. 1455, St. Thomas Neurosurgical Answer, Pg. 91-92 at ¶¶ 56, 66; Pg. 100 at ¶¶ 72, 74 The Saint Thomas Entities Answer contains nearly identical allegations. Dkt. No. 1464, St. Thomas Entities Answer, Pg. 108 at ¶¶ 272, 279; Pg. 115 at ¶¶ 288 and 290.

80. The Defendants promptly complied with all instructions from the Tenn. DoH and CDC regarding contacting patients, including an initial directive from the Tenn. DoH not to mention meningitis.

81. The Defendants relied upon and promptly complied with all directives and guidance received from the Tenn. DoH related to this fungal meningitis outbreak.

82. If it is established that the Tenn. DoH did not recommend appropriate notification of patients, the Defendants are constrained to assert comparative fault against the Tenn. DoH.⁵

Although the Saint Thomas Defendants alleged comparative fault against the TBoP and the TDoH, Saint Thomas Neurosurgical only proffered expert witnesses to opine on the actions of the FDA and the MBoP (the Saint Thomas Entities proffered no expert witnesses on these comparative fault defenses). Those expert witnesses have offered the following opinions:

[I]f FDA had exercised its enforcement authority over NECC...the fungal meningitis outbreak of 2012 would not have occurred.⁶

[T]he FDA and [MBoP] failed to exercise proper regulatory authority over NECC and failed to take the objectively reasonable regulatory actions that would have prevented the fungal meningitis outbreak of 2012. The FDA and the [MBoP] are both at fault...⁷

Based on the allegations in their Answer and the only expert testimony they intend to offer on the issue of the comparative fault of the Non-Party Governmental Entities, it is clear that the Saint Thomas Defendants seek to ascribe fault to those regulatory authorities on a theory that those entities should have done a better job of regulating NECC prior to the catastrophe of 2012, and their failure to properly regulate NECC is, in part, the cause of plaintiffs' injuries.

RULE 56 STANDARD

⁵ Dkt. No. 1455, St. Thomas Neurosurgical Answer, Pg. 101-102 at ¶¶ 80-82. The Saint Thomas Entities Answer contains nearly identical allegations. Dkt. No. 1464, St. Thomas Entities Answer, Pg. 116 at ¶¶ 295-297.

⁶ Expert Report of Sheldon Bradshaw, Esq., Pg. 30.

⁷ Expert Report of Dr. Henry Miller, Pg. 29.

Summary judgment should be granted when “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(a). In determining whether there is a genuine dispute, the Court “must view the evidence in the light most favorable to the opposing party.”⁸ When the party having the burden of proof on the issue at trial cannot establish a necessary element of his or her claim, summary judgment against that party is appropriate.⁹

In such circumstances, the moving party bears the initial burden of demonstrating the absence of any genuine dispute as to a material fact of consequence and supporting that motion with “affidavits, admissions, or other materials of evidentiary quality.”¹⁰ “Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial,” and summary judgment should be granted in favor of the movant.¹¹

ARGUMENT

I. Under the Public Duty Doctrine, Fault Cannot Be Attributed to Non-Party Government Agencies Because the Defendants Cannot Establish the Required Element of Individual Duty.

Under Tennessee law, establishing a legal duty is an essential element of establishing fault.¹² Fault cannot be established when no individual duty exists.¹³ “The existence or nonexistence of a duty owed to the plaintiff by the defendant is entirely a question of law for the court.”¹⁴

⁸ *Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014) (internal quotations and citation omitted).

⁹ *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

¹⁰ *Prall v. City of Boston*, 985 F. Supp. 2d 115, 119 (D. Mass 2013) (citing *Mulvihill v. Top-Flite Golf Co.*, 335 F.3d 15, 19 (1st Cir. 2003)).

¹¹ *Scott v. Harris*, 550 U.S. 372, 380 (2007) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986)).

¹² *Eaton v. McLain*, 891 S.W.2d 587 (1994).

¹³ *Id.*

¹⁴ *Hurd v. Flores*, 221 S.W.3d 14, 18 (Tenn. Ct. App. 2006).

The existence of a duty is a condition precedent to attributing fault in Tennessee. For an entity to be attributed the legal fault for any injury, a legal duty to prevent or not cause that harm must exist. A duty of care is “the legal obligation owed by defendant to plaintiff to conform to a reasonable person standard of care for the protection against unreasonable risks of harm.”¹⁵ “The common law has long recognized that an individual has a duty to exercise reasonable care in his or her activities in order to prevent unreasonable risks of harm from arising.”¹⁶ “While individuals have an obligation to refrain from acting in a way that creates an unreasonable risk of harm to others, the law generally does not impose on individuals an affirmative duty to aid or protect others.”¹⁷

Courts in Tennessee regularly dismiss claims attempting to ascribe fault to parties where no legal duty exists.¹⁸ As the Tennessee Supreme Court makes abundantly clear, “only after a duty is established does comparative fault come into play.”¹⁹ In the present case, fault cannot be attributed to government agencies because those agencies did not owe an individual duty to any particular plaintiff.

“As in any other negligence action, a [party] must establish the existence of a duty or standard of care in an action for negligence of a government employee.”²⁰ When a party asserts

¹⁵ Downs ex rel. Downs v. Bush, 263 S.W.3d 812, 819 (Tenn. 2008).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ See e.g., *Eaton* at 597 (dismissing claims after trial because “plaintiff has failed to present legally sufficient evidence as to the duty element on her claims...”); *Brient v. Petro PSC, L.P.*, 134 F.3d 370 (6th Cir. 1998) (dismissing claims where “as a matter of law [plaintiff] cannot establish the duty element of negligence.”); *Puckett v. Roberson*, 183 S.W.3d 643 (Tenn. Ct. App. 2005) (dismissing claims where no legal duty was shown because “[a]s a general rule, persons do not have a duty to control the conduct of other persons to prevent them from causing physical harm to others.”) *Norfleet v. Pulte Homes Tenn. Ltd. P’ship*, No. M2011-01362-COA-R3CV, 2011 WL 5446068, at *6 (Tenn. Ct. App. Nov. 9, 2011) (“Therefore, as a matter of law, [plaintiff] failed to establish an essential element of her claim, that of a duty owed to her by Defendant as it pertained to the step from the foyer to the sunken living room.”).

¹⁹ *Coln v. City of Savannah*, 966 S.W.2d 34, 42 (Tenn. 1998); see also *Blair v. Campbell*, 924 S.W.2d 75 (Tenn. 1996) (“Adoption of principles of comparative fault do not alter analysis applicable to common-law concept of duty.”).

²⁰ *Wells v. Hamblen County*, 2005 Tenn. App. LEXIS 510, *1 (Tenn. Ct. App. Aug. 22, 2005)

the fault of a public employee or entity, Tennessee courts follow a legal doctrine known as the public duty doctrine.²¹ Under that legal principle, duties owed by public employees and agencies are owed to the general public, not to specific individuals.²² Under the public duty doctrine, a duty owed to everyone is a duty owed to no one as far as tort liability is concerned.²³ The Tennessee Court of Appeals explains the public duty doctrine as follows:

The public duty doctrine is a creature of common law, and its purpose is to shield a public employee from “suits for injuries that are caused by the public employee’s breach of a duty owed to the public at large.” 6 *Ezell*, 902 S.W.2d at 397. It is sometimes explained by stating that a duty owed to everyone is a duty owed to no one. See *Brown*, 126 S.W.3d at 43.

As in any other negligence action, a plaintiff must establish the existence of a duty or standard of care in an action for negligence of a government employee. *Ezell*, 902 S.W.2d at 397, 400. In Tennessee, it has long been held that a plaintiff must show the existence of a duty particular to him or her, as distinct from a duty owed to the public in general.²⁴

Therefore, Tennessee law clearly provides that fault cannot be attributed to the Non-Party Governmental Entities because any duties owed by those agencies are owed to the general public, not to any particular plaintiff.

In *Hurd v. Flores*, for example, a motorist claimed that a police officer negligently caused the motorist’s accident by not stopping the driver from entering an interstate crossover within sight of the officer.²⁵ The Court of Appeals dismissed the matter under the public duty doctrine, stating that, although the officer had a duty to preserve the peace and arrest lawbreakers, that duty “is one which the officer owes to the public generally, and not to particular individuals, and [] the breach of such duty accordingly creates no liability on the part

²¹ *Ezell v. Cockrell*, 902 S.W.2d 394, 397-401 (1995).

²² *Id.* at 397.

²³ *Brown v. Hamilton County*, 126 S.W.3d 43, 48 (2003).

²⁴ *Wells v. Hamblen County*, No. E2004-01968-COA-R3-CV, 2005 Tenn. App. LEXIS 510, at *1 (Tenn. Ct. App. Aug. 22, 2005).

²⁵ 902 S.W.2d at 19.

of the officer to an individual who was damaged by the lawbreaker's conduct."²⁶ Accordingly, with respect to the officer's general public duty, the public officer's conduct was "amenable only to the public, and punishable only by indictment for breach of his duty as conservator of the peace."

There are several sound public policy considerations advanced to explain and support the public duty doctrine.²⁷ One such public policy consideration is particularly instructive in the present litigation. Tennessee courts recognize that "individuals, juries, and courts are ill-equipped to judge governmental decisions as to how specific community resources should be or should have been allocated to protect individual members of the public."²⁸ To allow the Saint Thomas Defendants to try a comparative fault defense against the Non-Party Governmental Entities for allegedly failing to shut down NECC prior to the fungal meningitis catastrophe would invite the jurors to attempt to answer the question of how much resources the FDA, MBoP and the TBoP should have devoted to investigating one particular compounding pharmacy. Tennessee courts have long recognized that jurors are simply ill-equipped to answer such questions and that accountability of public agencies is better left to the political process.²⁹

Although the public duty doctrine frequently arises in the context of police officers sued for allegedly failing to enforce laws, the public duty doctrine applies to all governmental entities and employees that have a duty to enforce laws.³⁰ In fact, the Tennessee Court of Appeals

²⁶ *Id.* at 27-28.

²⁷ *Eldridge v. City of Trenton*, Appeal No. 02A01-9503-CV-0041, 1997 Tenn. App. LEXIS 573, 1997 WL 527303 (Tenn. Ct. App. Aug. 26, 1997) (discussing the public policy considerations behind Tennessee's public duty doctrine).

²⁸ *Id.*

²⁹ *Hurd*, 221 S.W.3d at 20 (public officials are "amenable only to the public, and punishable only by indictment for the breach of [duties]" owed to the public generally.)

³⁰ *Karnes v. Madison Cnty.*, No. W209-02476-COA-R3-CV, 2010 Tenn. App. LEXIS 589, 2010 WL 3716458 (Tenn. Ct. App. Sept. 23, 2010) ("Succinctly stated, the [public duty] doctrine provides that private citizens cannot maintain an action against public officials or entities unless they are able to allege a special duty not owed to the public generally.") *citing Hurd* 221 S.W.3d at 28. *Wells*, 2005 Tenn. App. LEXIS 510, 2005 WL 2007197, at *3.

recently applied the public duty doctrine in a similar context as the one at issue in the present litigation. In *Kemper v. Baker*, the Tennessee Court of Appeals held that a building inspector could not be attributed any fault in a case where the plaintiff alleged negligence based on “the failure of the city and the city manager to enforce certain OSHA regulations and provisions of the municipal building code.”³¹ The Court of Appeals held that the city could not be liable for any negligent failure to enforce the building codes under the public duty doctrine.³²

Moreover, federal courts routinely apply the public duty doctrine of state courts to actions of federal agencies, officials, and governmental entities. The Fourth, Seventh, Eighth, and Ninth Circuit Courts of Appeals have all applied state law public duty doctrines in cases involving claims that agents of the United States government failed to properly enforce federal law.³³

“As in any other negligence action, a [party] must establish the existence of a duty or standard of care in an action for negligence of a government employee.”³⁴ “In Tennessee, it has long been held that a plaintiff must show the existence of a duty particular to him or her, as distinct from a duty owed to the public in general.”³⁵ Accordingly, because the Saint Thomas Defendants cannot establish the required element of individual duty, those defendants cannot ascribe fault to the government regulators at trial, and those regulators cannot be placed on the verdict form.

(“In Tennessee, it has long been held that a plaintiff must show the existence of a duty particular to him or her, as distinct from a duty owed to the public in general.” In other words, under the public duty doctrine, “a duty owed to everyone is a duty owed to no one.”); *Lynch v. Loudon Cty.*, No. E2010-02231-COA-R3CV, 2011 WL 4952778, at *5 (Tenn. Ct. App. Oct. 14, 2011) (“The public duty doctrine shields a public employee from lawsuits alleging liability for a breach of that employee’s duty owed to the public at large.”) citing *Ezell*, 902 S.W.2d 394.

³¹ *Kemper v. Baker*, No. M2011-00407-COA-R3CV, 2012 WL 1388371, at *1 (Tenn. Ct. App. Apr. 19, 2012)

³² *Id.* at *6.

³³ *Fla. Auto Auction of Orlando, Inc. v. United States*, 74 F.3d 498, 503 (4th Cir. 1996); *Stratmeyer v. United States*, 67 F.3d 1340, 1347 (7th Cir. 1995); *Sorace v. United States*, 788 F.3d 758, 766 (8th Cir. 2015); *Saunders v. United States*, 99 F. App’x 814, 816 (9th Cir. 2004); see also *Perez v. Gov’t of the Virgin Islands*, 847 F.2d 104 (3d Cir. 1988).

³⁴ *Wells v. Hamblen County*, No. E2004-01968-COA-R3-CV, 2005 Tenn. App. LEXIS 510, *1 (Tenn. Ct. App. Aug. 22, 2005).

³⁵ *Id.*

II. The Saint Thomas Defendants Have No Proof That The TBoP or the TDoH Caused Any Plaintiffs' Injury

Notwithstanding the fact that the public duty doctrine bars the Saint Thomas Defendants' comparative fault defenses alleging fault by the Non-Party Governmental Entities, there exists a separate and independent reason to dismiss claims of comparative fault alleged against the TBoP and the TDoH: the Saint Thomas Defendants have offered no proof of actual or legal causation.

It is black-letter Tennessee law that "[p]roof of negligence without proof of causation is nothing."³⁶ Indeed, in determining whether an actor was legally negligent under Tennessee law, causation and proximate cause both must be proven by a preponderance of the evidence.³⁷ The alleged comparative fault of third parties is no different: an element of third-party fault requires proof that the allegedly negligent conduct caused the plaintiff's injuries.³⁸

The Saint Thomas Defendants took no deposition of any TBoP or TDoH representatives that could support causation in this instance, and they have offered no expert witness who is willing and able to opine on the causal connection between any action or inaction of the TBoP and/or the TDoH to sustain a claim of comparative fault. Without proof, the Saint Thomas Defendants therefore cannot establish the requisite element of causation with respect to the TBoP or TDoH. Accordingly, summary judgment is appropriate, at a minimum, against those entities.³⁹

³⁶ *Doe v. Linder Constr. Co.*, 845 S.W.2d 173 (Tenn. 1992) ("Proof of negligence without proof of causation is nothing.") (quoting *Drury v. Cnty. of Obion*, 619 S.W.2d 397, 398 (Tenn. Ct. App. 1981)).

³⁷ See *Kilpatrick v. Bryant*, 868 S.W.2d 594, 598 (Tenn. 1993) ("Causation and proximate cause are distinct elements of negligence, and both must be proven . . . by the preponderance of the evidence.");

³⁸ *Parsons v. Wilson Cnty.*, No. M2014-00521-COA-R3-CV, 2015 Tenn. App. LEXIS 719, at *13 (Tenn. Ct. App. Sept. 3, 2015) (stating that, with respect to the comparative fault of third parties, " 'Fault' includes not only allegedly negligent or other tortious conduct that contributed to cause plaintiff's injury, death, or losses, but also any conduct that allegedly 'caused' plaintiff's injury, death, or losses.") (quoting 17 John A. Day, *et al.*, *Tenn. Practice: Tennessee Law of Comparative Fault* s. 12:1 (2015)).

³⁹ See *Kilpatrick v. Bryant*, 868 S.W.2d 594, 598 (Tenn. 1993) ("Causation and proximate cause are distinct elements of negligence, and both must be proven . . . by the preponderance of the evidence."); see also *Parsons v. Wilson Cnty.*, 2015 Tenn. App. LEXIS 719 (Tenn. Ct. App. Sept. 3, 2015) (stating that, with respect to the comparative fault of third parties, " 'Fault' includes not only allegedly negligent or other tortious conduct that contributed to cause plaintiff's injury, death, or losses, but also any conduct that allegedly 'caused' plaintiff's injury,

CONCLUSION

Tennessee law does not allow the defendants to blame the government at trial. For the forgoing reasons, the PSC requests the entry of a partial summary judgment order dismissing the Saint Thomas Defendants' alleged affirmative defense of comparative fault against the FDA, the Massachusetts Board of Registration in Pharmacy, the Tennessee Board of Pharmacy, and the Tennessee Department of Health.

Respectfully Submitted This 19th Day of May, 2016,

/s/ J. Gerard Stranch, IV

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CERTIFICATE OF SERVICE

I, Gerard Stranch, hereby certify that on May 19, 2016, I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

/s/ J. Gerard Stranch, IV

J. Gerard Stranch, IV